

# **National Smallpox Readiness Update**

**Secretary's Council on Public Health Preparedness  
September 22, 2003**



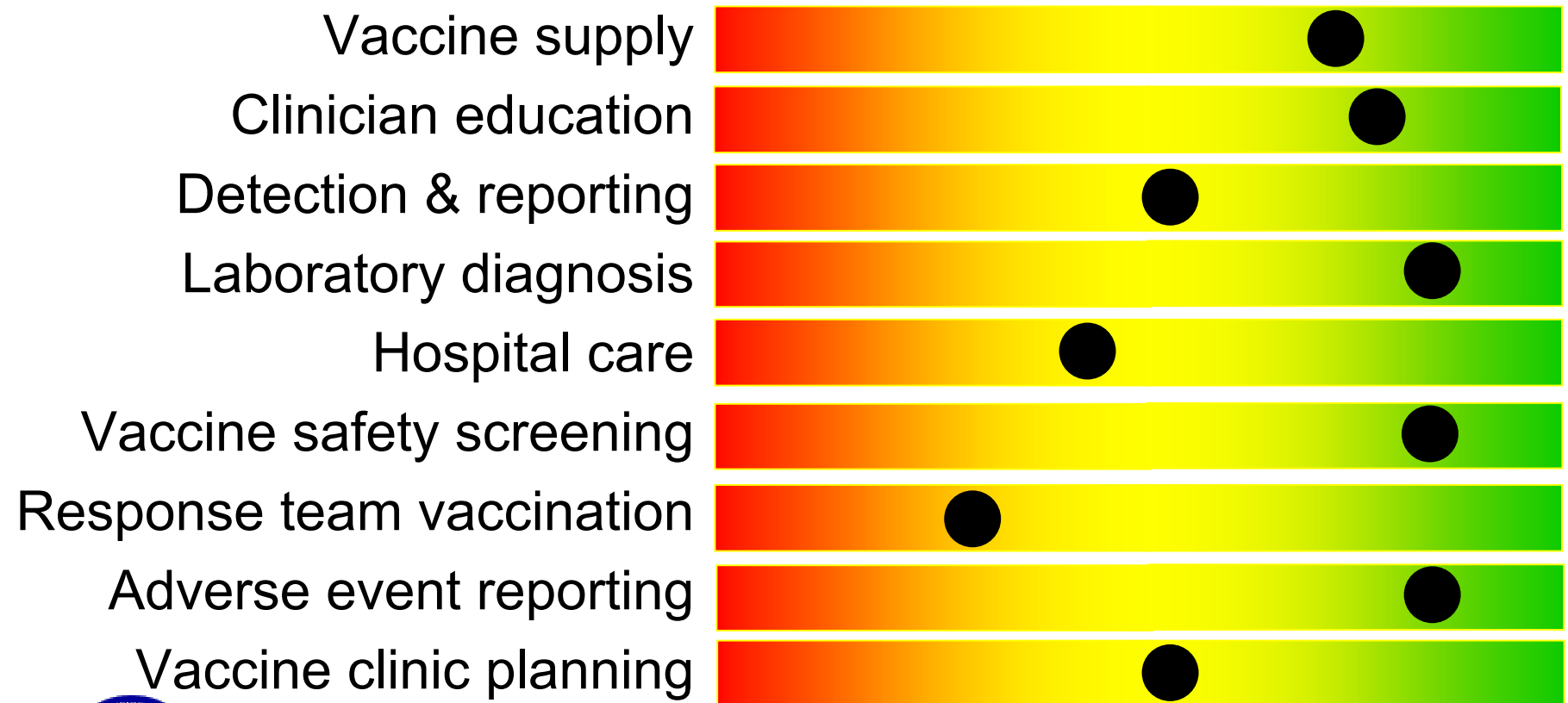
# Smallpox Preparedness Program Overview

- Smallpox threat: not quantifiable, but not zero
- Smallpox exposure consequences: severe in an unvaccinated population
  - Unless the Nation achieves comprehensive smallpox preparedness
- Presidential policy decision December 2002:
  - HHS to work with State and local governments to form volunteer smallpox response teams
  - Healthcare workers and other critical personnel asked to volunteer to be vaccinated
  - Vaccination not recommended for the general public
  - DOD and State to vaccinate at-risk personnel
- Goal: prepare and protect key staff prior to an event and sufficient preparedness to vaccinate the entire population in 10 days post-event



# CDC Assessment of National Smallpox Preparedness

## September 2003

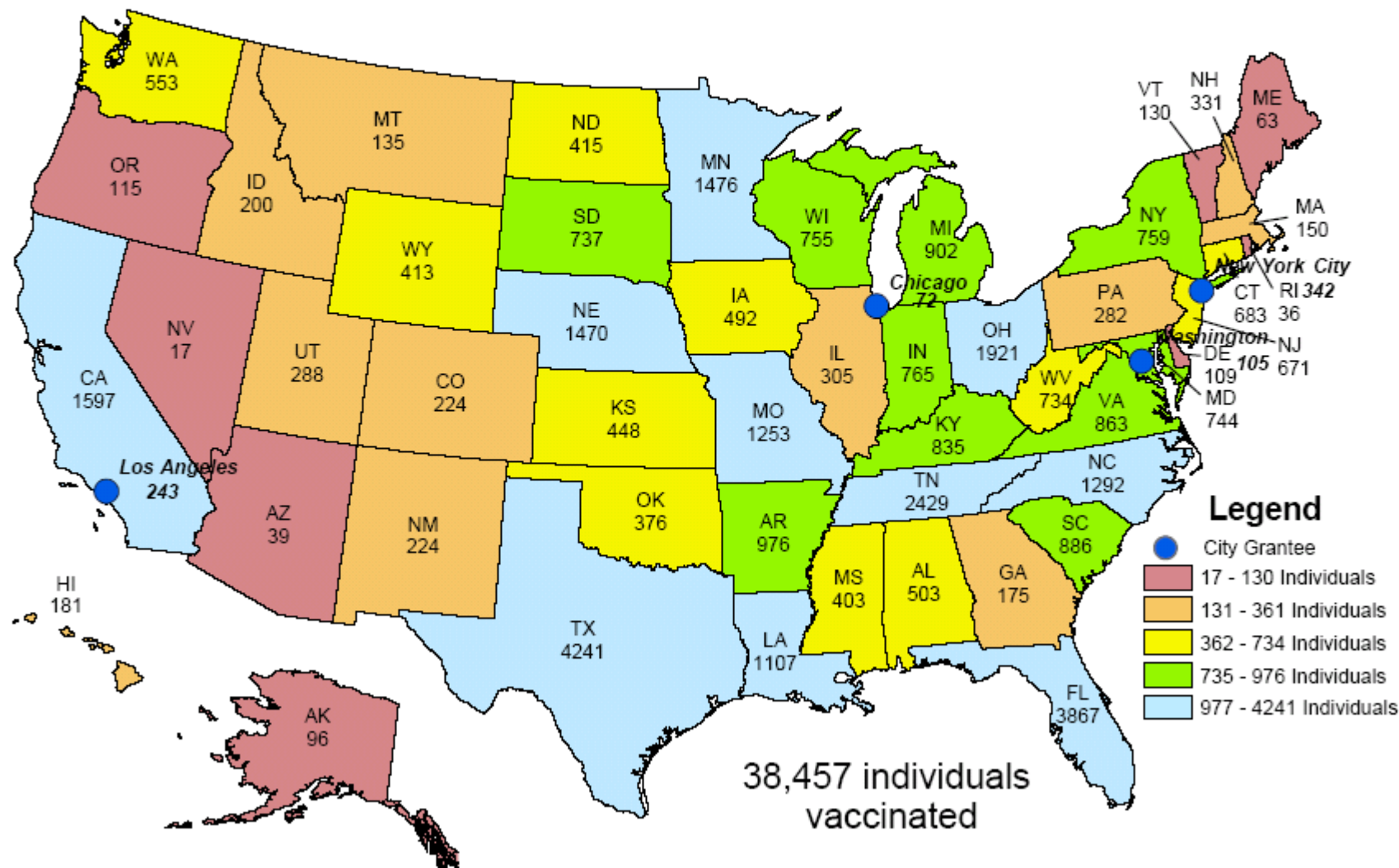


Red = Less Prepared  
Yellow = Moderate Progress  
Green = Highly Prepared



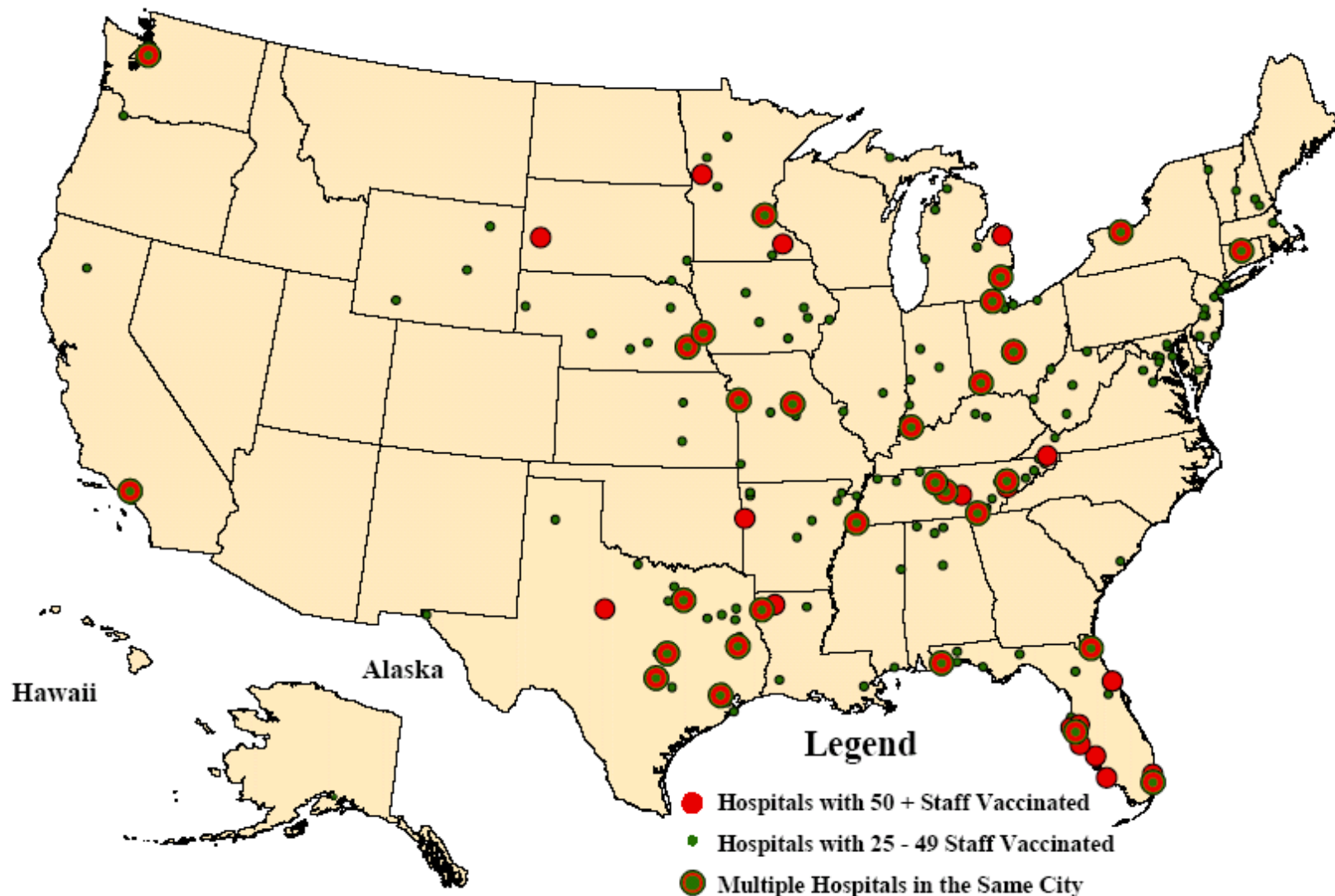


# National Immunization Program Number of Individuals Vaccinated As of September 12, 2003

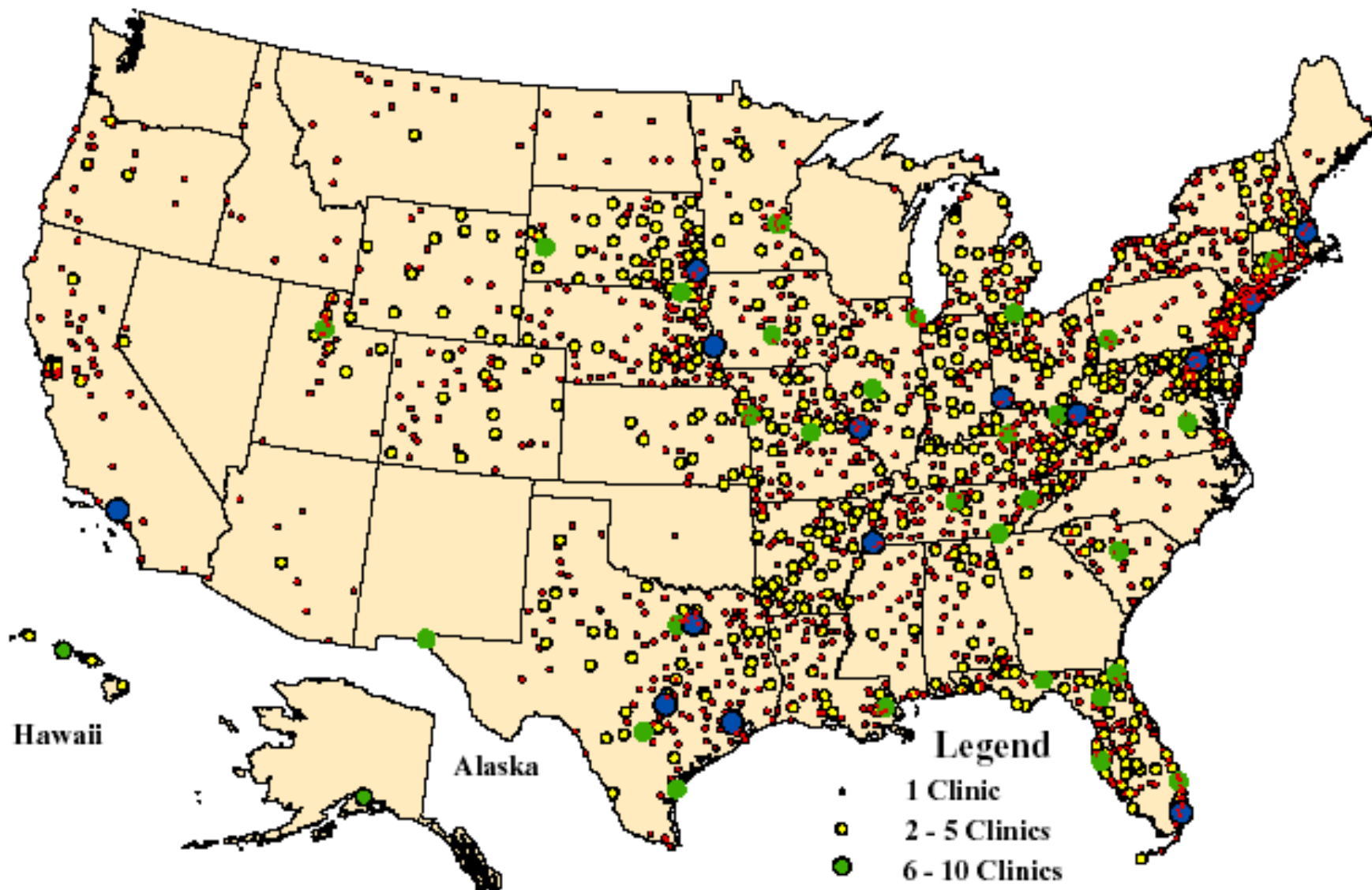




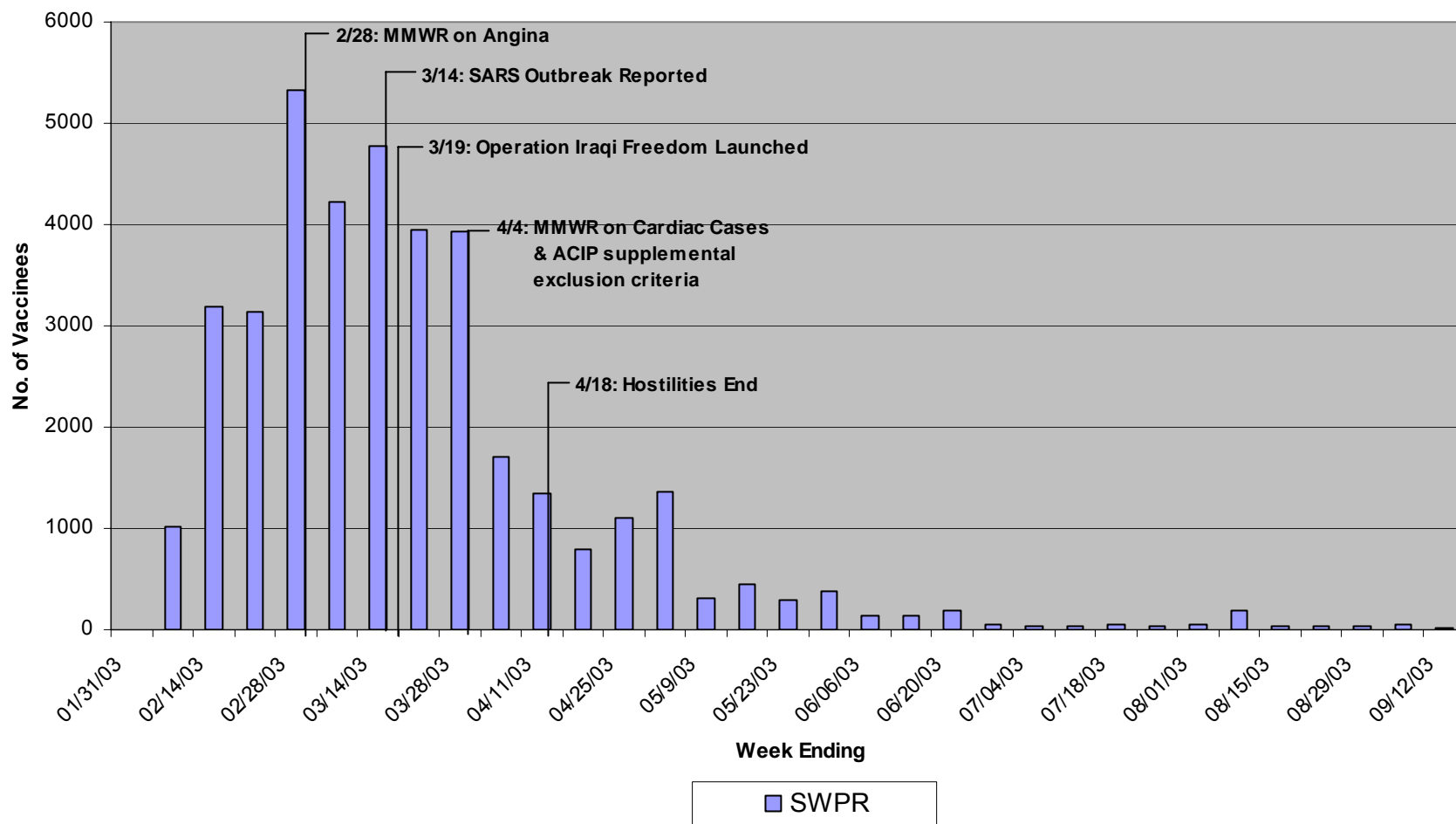
# National Immunization Program Smallpox Healthcare Response Team Preparedness As of September 12, 2003



# National Immunization Program Smallpox Vaccination Clinic Locations As of July 15, 2003



## Smallpox Weekly Progress Report (SWPR) Weekly Count of Vaccinations



# Vaccination Summary

## 1/24/03 - 9/12/03

- Number vaccinated: 38,457
  - Public health: 11,575
  - Health care: 24,963
  - Other: 1,919
- Female: 65%
- Primary vaccinees: 25%
- Age distribution: 80%  $\geq$  40 years
- Take response
  - All vaccinees: 92%
  - Primary vaccinees: 90.3%
  - Revaccinees: 92.5%





# Smallpox Vaccine Adverse Events Monitoring and Response System

- Clinical Consultation
  - State health departments
  - Health care providers
- Surveillance
  - Active and passive
  - National, state, hospital
  - Review of all reports
  - Investigation of serious reports
- Technical Assistance to States



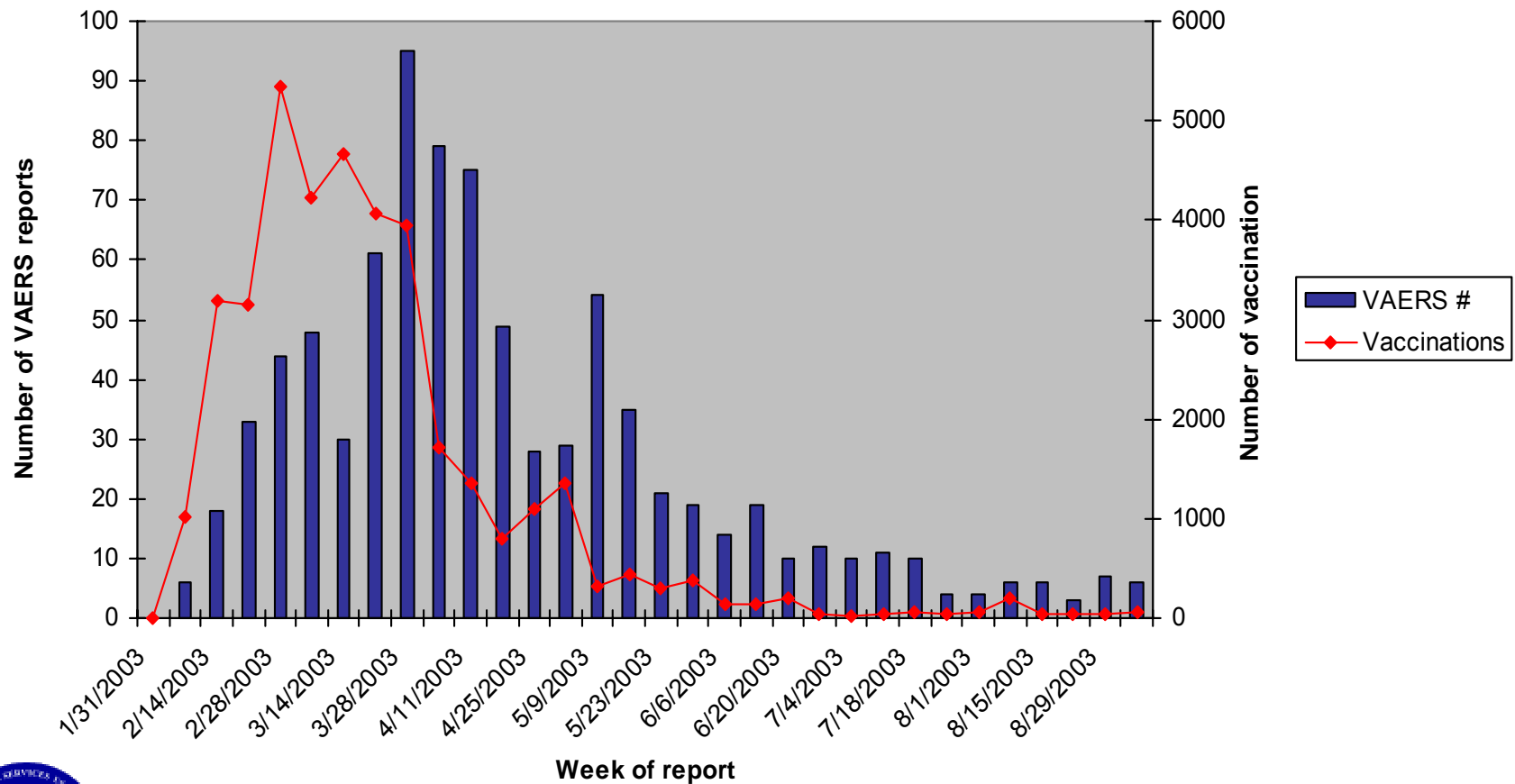
# Adverse Event Overview

## 1/24/03 – 9/05/03

- 801 civilian reports
- >99% report only smallpox vaccine
- ~67% revaccinees
- 76% female
- 67% from persons aged 40-59 years
- 88% non-serious by regulatory criteria
- Reporting rates per 1,000 doses administered
  - All reports: 20.7
  - Serious reports: 2.4



# Weekly Count of Vaccinations and VAERS Civilian Smallpox Reports



In civilian program, **no reports of:**

Eczema vaccinatum

Erythema multiforme major

Fetal vaccinia

Progressive vaccinia

Vaccinia transmission to contacts



# Preventable Expected Adverse Events

## Inadvertent Inoculation

- 21 non-ocular cases
  - 7 cases non-ocular autoinoculation (6 suspected and 1 confirmed)
  - 14 contact transmission (DoD to civilian)
- 3 cases of ocular autoinoculation
  - 1 suspected and 2 confirmed
  - 2 of the 3 from contact transmission (DoD to civilian)
- No reported cases of civilian-to-civilian or nosocomial contact transmission



# Non-preventable Expected Adverse Events

## **Suspected Post-vaccinial Encephalitis** [MMWR 2003.52(20):475-77]

- Meets case definition but atypical features
- Hospitalized (3)
  - Acute epiglottitis (10d post-vaccination)
  - Steroid-induced psychosis
  - Post-infectious encephalomyelitis

## **Generalized Vaccinia**

- 2 suspected, 1 PCR confirmed
- Onset 2, 8, 10 days post-vaccination
- Benign clinical course



# Unexpected Adverse Events

## Cardiac events

- Ischemic Events (n=8)
- Myo/pericarditis (n=22)
  - Historically only rare reports in US
  - Case reports in Europe and Australia
  - Different vaccine strain
- Dilated cardiomyopathy (n=2)



# Ischemic Cardiac Events (n=8)

- 5 MIs; 3 angina
- 2 (25%) female
- Median age: 57 years (range 46 – 65 y)
- All revaccinees
- Median time to symptom onset: 8 days (0-26 d)
- 5 (62%) met exclusionary criteria
  - History of CAD or  $\geq$  3 cardiac risk factors
- All hospitalized; 2 deaths, 6 survivors
  - Incident cases either do not exceed expected number (angina) or are within the 95% predictive interval (MI)
  - There is biological plausibility, but the data are inadequate to accept or reject a causal relationship.



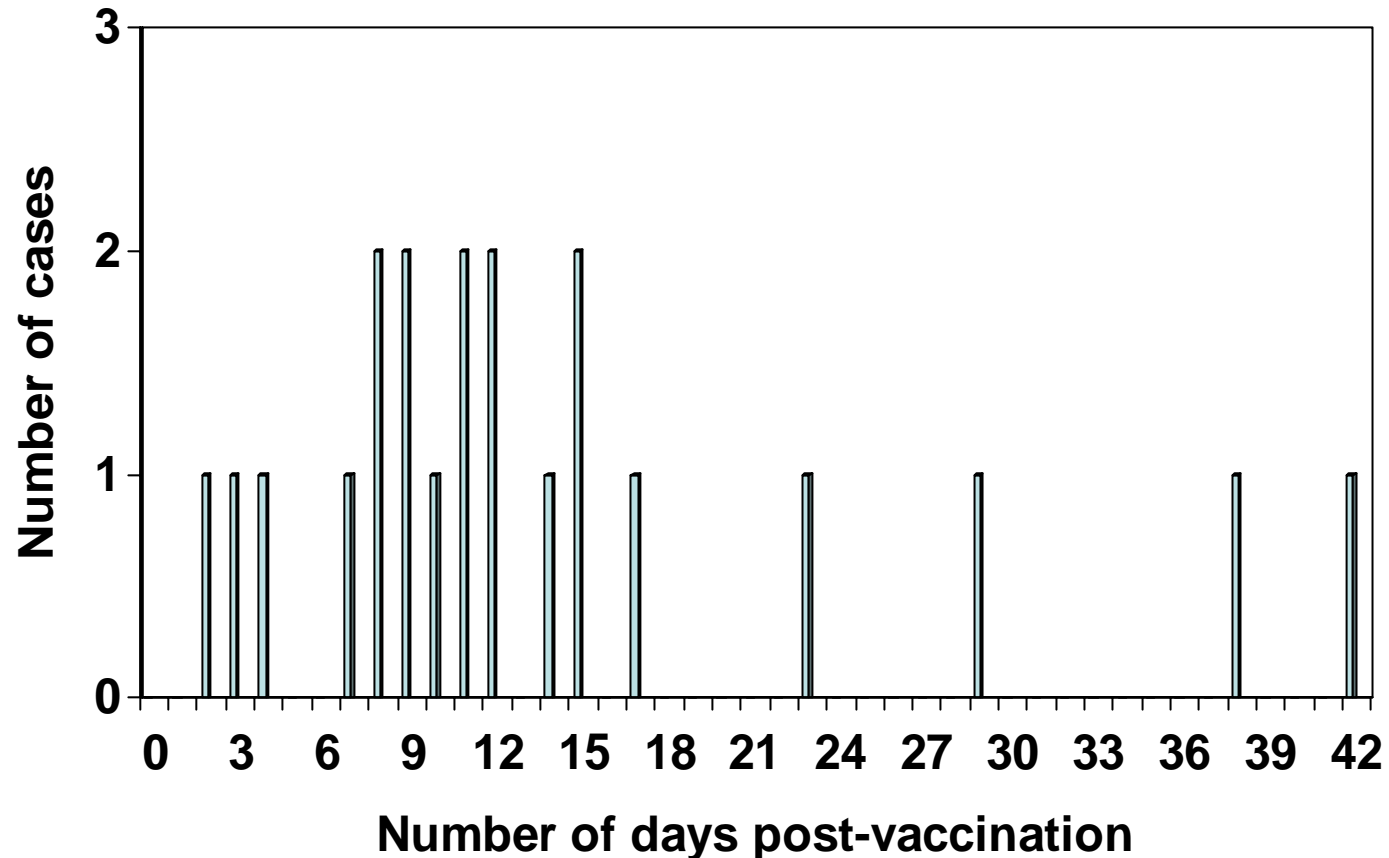


# Myo/pericarditis (n=22)

- 14 (64%) female
- Median age: 48 Y (range 25 – 70 y)
- 19 (86%) revaccinees
- Median time to symptom onset: 12 d (1-73d)
- 46% hospitalized
- All survived
- Rate of 1.6/10,000 (probable cases, n=6)
- Suggestion of increased incidence rate 7 – 13 days post-vaccination, but not statistically significant



# Myo/pericarditis Onset Interval\*



\*N=21; additional case occurred on day 73



# Dilated Cardiomyopathy (DCM) Following Smallpox Vaccination

- 2 cases identified 3 months post-revaccination
  - Both female, aged 53 and 55 years
  - No evidence of common causes for DCM, although one with obesity
- DCM not previously reported following smallpox vaccination
- Because smallpox vaccination appears causally associated with myo/pericarditis and myocarditis is one cause of DCM, attention heightened for these cases.
- However, attributing causality in the 2 cases is difficult



# Other Serious Adverse Events

- Acute MI
- Angina
- Anoxic encephalopathy
- Appendicitis
- Arrhythmias
- Asthma
- Cancer: CNS, pancreatic
- Cerebral vascular accident
- Chest pain, non-cardiac
- Chest pain, non-specific
- Cholecystitis
- Dilated cardiomyopathy
- Facial paralysis
- GERD
- Headache
- Herpes Zoster
- Hypertension
- Neuropathy
- Pneumonia
- Prostatitis
- Sinusitis
- Transient global amnesia
- Urinary tract infection
- Vertigo
- Vomiting and diarrhea



# Early Pregnancy Outcomes of Women Exposed to Smallpox Vaccine

(Preliminary Findings)

- 12 civilian women inadvertently exposed to the smallpox vaccine in pregnancy:
  - 10 vaccine recipients
  - 2 close contacts of vaccine recipients
- Age distribution:
  - Range: 26 – 38 years
  - Mean: 31 years
- Vaccination status:
  - 3 out of 10 had received the vaccine previously
  - Vaccination status unknown for contacts



# Early Pregnancy Outcomes of Women Exposed to Smallpox Vaccine

## (Preliminary Findings)

- 3 spontaneous abortions:
  - 2 at 6 weeks
  - 1 at 10.4 weeks gestation
- Currently:
  - 1 in 1<sup>st</sup> trimester
  - 2 in 2<sup>nd</sup> trimester (1 placenta previa)
  - 4 in 3<sup>rd</sup> trimester (1 vasa previa)



# Adverse Events Summary

- Few adverse events historically associated with smallpox vaccine have been reported
- No contact transmission in civilian program
- A causal association between smallpox vaccination and myo/pericarditis appears likely
  - Based primarily on DoD data; evidence is less clear in civilian vaccinees
    - This is likely due to differences in the 2 populations (e.g., age, gender, prior vaccination status, case ascertainment) rather than status as military or civilian personnel.



# Adverse Events – Future Actions

- Continue educational and screening efforts and quantify impact
  - Enhance if program extends beyond response teams
- Continue surveillance and pregnancy registry for known and unexpected serious adverse events
- Provide guidance for prospective clinical evaluation of vaccinees with cardiac events
- Complete investigation and follow-up of vaccinees with cardiac events





# Challenges

- Public complacency:
  - Smallpox threat perceived to be near zero since end of the Iraq war
  - Smallpox preparation perceived to be low priority or not worth the risk
- Public health and hospital workforce that is:
  - Not fully engaged
  - Skeptical about the credibility of the smallpox threat
  - Confused about vaccination risks and available protections
- Vaccination of citizens who insist on being vaccinated:
  - Licensed vaccine in 2004
  - Current access limited to clinical trials
  - No other program initiated
  - Demand for vaccination is very small



# Action Plan -- HHS/CDC will:

- Increase national awareness of threat and safety of vaccine
  - Develop and implement a comprehensive communication strategy
  - Engage key opinion leaders, health professionals, and the public
  - Provide State and local health officials with updated smallpox threat briefing
  - Outline social and economic consequences of a smallpox attack
- Measure State and local preparedness
  - Link to national emergency public health preparedness performance measures
  - Score-card smallpox preparedness at state and local levels
- Work to add smallpox and bioterrorism preparedness standards into hospital accreditation process
- Weigh other techniques to speed post-attack vaccination, including
  - Deploy vaccine stocks to local or regional facilities (191,400 doses in the field)
  - Engage VA and DoD to supplement preparedness and response capacity
- Develop options to make vaccine available to citizens who insist on vaccination



# **Smallpox Readiness Score-card Elements**

- **Early detection, reporting, isolation, and treatment of cases**
- **Rapid investigation and prophylaxis of contacts**
- **Mass vaccination such that the entire population is vaccinated within 10 days of first confirmed case**
- **Assure critical messages and materials are provided to the public before, during, and after response**
- **Laboratory capacity to confirm smallpox disease and rule-out other rash illnesses**
- **Management of vaccine supplies**
- **Drills and exercises to test proficiency**
- **Data and information management and**
- **Voluntary vaccination and training of key responders prior to an outbreak**

